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Media Release





Basel, 15. April 2005

Roche clinical trial registry and results database launched on www.roche-trials.com

High degree of transparency to enhance communication between Roche, patients and doctors

Within only three months after deciding to create an electronic database, Roche is launching a public clinical trial registry and results database using an independent host, CenterWatch. On www.roche-trials.com information on Roche's clinical trials can be accessed by anyone, anywhere, with no password restrictions. This site is designed to give patients and healthcare providers ready access to information they need, in terms they can understand.

Ed Holdener, Head of Global Pharma Development at Roche, said: "We are proud to go live with our publicly accessible protocol registry and clinical trial results database today. Transparency has always been and continues to be a priority for us. In January, we announced our plans to have an independent host for the database and since then, we selected CenterWatch, a company with a wealth of experience in the area of data management and the publication of clinical trial information. So for the first time ever, there is now a global and publicly accessible database, containing comprehensive information about Roche's clinical trials".

Roche expects that the huge task of publishing data from more than 30 medicines, on a product by product level from a large number of global and local trials, will take approximately a year.

Roche will also continue to contribute information to established databases (i.e.

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Information that can be found in the electronic database

Starting with Fuzeon and Bondronat, clinical trial information will be added in a staged approach on the databases and will ultimately include protocol information and results from all Phase II to Phase IV clinical trials completed after 1 October, 2004. In addition, data from all Phase II to

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Tel. 061 - 688 88 88 Fax 061 - 688 27 75 http://www.roche.com Phase IV clinical trials for medicines first marketed after 1 October, 2002 will be included retrospectively. The clinical trial registry and results database will also include interventional clinical studies from Roche Diagnostics.

Roche approach and possible industry solution

Roche is taking a leadership role in the industry's efforts to ensure transparency with its global approach, which is consistent with the information disclosure principles published earlier this year by the European Federation of Pharmaceutical Industry Associations (EFPIA).

The Roche strategy may model an industry-wide solution. Roche would support and participate in a future industry solution that provides a public database in which all companies can publish both national and international protocol information and trial results. Roche would be delighted if this independent solution would lead other pharmaceutical companies to use the CenterWatch repository to register ongoing clinical trials and report results of trials.

CenterWatch is a leader in web design and experienced in the implementation of websites for clinical trial listings and clinical trial results, and already has an established reputation as an independent source that the public trusts for clinical trial listings and results. Having CenterWatch host Roche's clinical trials databases provides the widest possible exposure, and makes it easy for the public to obtain important information in this area.

Strict adherence to regulations of clinical trials

Roche works to ensure that all its activities are performed in accordance with ethical and regulatory requirements. Moreover, Roche is strongly committed to verifying adherence to compliance policies. Adequate and ongoing peer review is a key prerequisite for maintaining high ethical standards in Roche's clinical trials and development activities.

In addition, Roche adheres to the "Declaration of Helsinki", a statement developed by the World Medical Association on ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Roche also strictly follows the rules of good clinical practice (GCP), which ensure the protection of patients' safety and rights.

About CenterWatch

Thomson CenterWatch (CW) is part of Thomson Healthcare and Scientific, probably best known as publishers of the PDR (Physician's Desk Reference) and Current Drugs. Thomson Healthcare and Scientific is a division of the Thomson Corporation, a Canadian based information services provider. For over a decade, CW has been the leading provider of clinical trials information to healthcare professionals and the patient community. Their market intelligence data and editorial content is highly respected among global pharmaceutical industry professionals. They publish

eight top-selling guidebooks covering training issues for today's clinical research professionals. In 1995 CW launched the <u>www.centerwatch.com</u> web site and began publishing listings of clinical trials seeking patient volunteers. The oldest and largest trial database on the web, the Clinical Trials Listing ServiceTM now lists nearly 15,000 industry-sponsored clinical trials, as well as an additional 20,000 clinical trials sponsored by the NIH and NCI. In 2004 alone, nearly 10 million people will visit the site directly or access information through their vast network of content partners.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004 sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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Further information

- Roche and clinical trials: www.roche.com/sus res clin
- Clinical trials: www.roche.com/sci events facets clinical
- EFPIA position statement: www.efpia.org/4_pos/sci_regu/Clinicaltrials2005.pdf
- Declaration of Helsinki: www.wmg.net/e/policy/b3.htm

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Media Release



Basel, 15 April 2005

Avastin produces significant benefit in first-line metastatic breast cancer Interim analysis shows improved progression-free survival with Avastin for patients with previously untreated metastatic breast cancer – the third cancer to show benefit with Avastin

Roche and Genentech, Inc., announced today that Avastin (bevacizumab, rhuMAb-VEGF) in combination with chemotherapy, significantly improves progression-free survival in patients with previously untreated, metastatic breast cancer. This is in addition to the positive survival benefit with Avastin observed in advanced colorectal cancer and the recently announced data in locally advanced or metastatic non-small cell lung cancer.

Eight to nine percent of women will develop breast cancer during their lifetime, making it one of the most common types of cancer in women. Each year more than one million new cases of breast cancer are diagnosed worldwide, with a death rate of approximately 410,000 people per year.

"The results of this study are outstanding as it is the third cancer where Avastin, in combination with chemotherapy, has shown significant clinical benefit," said William M. Burns, CEO of Roche's Pharmaceutical Division. "This study underlines the importance of targeting angiogenesis in the therapy of patients with cancer to significantly improve treatment outcome. We plan to share these data with the regulatory authorities in order to explore with them how Avastin can be made available to patients with metastatic breast cancer."

Avastin, an anti-angiogenesis drug, works by choking off the blood supply that is essential for the growth of the tumour and its spread throughout the body. The phase III study investigated the use of Avastin in combination with paclitaxel chemotherapy in patients who had not received any previous treatment for their metastatic disease (first-line). The companies were advised by the trial group conducting the study, that an interim analysis of the study showed that it met its primary efficacy endpoint of improving progression-free survival, the length of time the cancer is

stable, compared to chemotherapy alone.

About the study

This is the first phase III study to evaluate Avastin in combination with chemotherapy for the first-line treatment of metastatic breast cancer. This randomised, controlled, multi-centre study enrolled 722 women with previously untreated metastatic breast cancer. The study was sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health, and conducted by a network of researchers led by the Eastern Cooperative Oncology Group (ECOG). The patients were randomised to receive treatment with paclitaxel with or without Avastin. Patients with HER2-positive metastatic breast cancer were not enrolled in the study unless they had received prior treatment with Herceptin (trastuzumab) or were unable to receive treatment with Herceptin. Patients who had received adjuvant paclitaxel within the previous 12 months and patients with a prior history of blood clots or who were receiving blood thinners were also excluded from the study. According to ECOG, data from this study will be submitted to an upcoming medical meeting.

Preliminary analysis of the data shows that adverse events in this study were similar to those observed in previous clinical trials with Avastin in combination with chemotherapy in metastatic breast cancer.

About Avastin

Avastin is the first treatment that inhibits angiogenesis – the growth of a network of blood vessels that supply nutrients and oxygen to cancerous tissues. Avastin targets a naturally occurring protein called VEGF (Vascular Endothelial Growth Factor), a key mediator of angiogenesis, thus choking off the blood supply that is essential for the growth of the tumour and its spread throughout the body (metastasis).

In Europe, Avastin is approved for first-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with the chemotherapy regimens of intravenous 5-fluorouracil/folinic acid/irinotecan. Avastin received fast-track approval by the US Food and Drug Administration (FDA) and was launched in the US in February 2004.*

In the pivotal Phase III study, the addition of Avastin to chemotherapy (irinotecan/5-fluorouracil/leucovorin) significantly extended survival by, on average, five months (20.3 months versus 15.6 months) for people with previously untreated metastatic colorectal cancer. Avastin

also significantly increased the amount of time the cancer was not growing compared with patients receiving chemotherapy alone (10.6 months vs. 6.2 months). In a second Phase III study, conducted by the Eastern Cooperative Oncology Group (ECOG), Avastin was also shown to significantly improve survival when added to another widely prescribed chemotherapy regimen (oxaliplatin/5-fluorouracil/leucovorin). With Avastin, people who had previously failed one chemotherapy regimen for their advanced disease, lived nearly two months longer, on average, compared to those who received chemotherapy alone (12.5 months vs. 10.7 months).

People with very advanced colorectal cancer who are too unwell to tolerate traditional aggressive chemotherapy also benefit from Avastin. The addition of Avastin to a less aggressive form of chemotherapy increased the length of time the cancer was not growing, by four months, compared to chemotherapy alone (a 67 percent increase in progression-free survival).

Roche and Genentech are pursuing a comprehensive clinical programme investigating the use of Avastin in advanced colorectal cancer with other chemotherapies and also expanding into the adjuvant setting (post operation). As its mechanism may be relevant in a number of malignant tumours, Roche and Genentech are also investigating the potential clinical benefit of Avastin in pancreatic cancer, ovarian cancer, renal cell carcinoma and others. Approximately 15,000 patients are expected to be enrolled into clinical trials over the next years worldwide.

About Roche

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Further information:

- Genentech; www.gene.com
- Cancer: www.health-kiosk.ch
- Roche in Oncology: www.roche.com/pages/downloads/company/pdf/mboncology05e_a.pdf-

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Note for editors

In the US, Avastin is approved for use in combination with intravenous 5-fluorourseil-based chemotherapy, for first-line treatment of patients with metastatic carcinoms of the colon or rectum.

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- Hurwitz H, Fehrenbacher L, Novotny W, et al. Bevacizumab plus Irinotecan, Fluorouracil, and Leucovorin for Metastatic Colorectal Cancer. New England Journal of Medicine 2004; 350(23): 2335–2342.
- 3. Mitchell EP, Alberts SR, Schwartz BJ, et al. High-dose bevacizumab in combination with FOLFOX4 improves survival in patients with previously treated advanced colorectal cancer: Results from the Eastern Cooperative Oncology Group (ECOG) study E3200. ASCO Gastrointestinal 2005 Cancer Symposium, January 2005 (abstract 169a).
- 4. Kabbinavar PF, Joseph Schulz J, McCleod M, et al. Addition of Bevacizumab to Bolus 5-FU/Leucovorin in First-Line
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Media Release



Basel, 12 April 2005

Roche and GlaxoSmithKline announce promotion agreement for Xenical in the US

Roche and GlaxoSmithKline Consumer Healthcare (GSK Consumer Healthcare) announced today that they have signed a promotion agreement for the prescription weight loss medication Xenical (orlistat) in the US. The agreement allows GSK Consumer Healthcare to detail and promote Xenical Rx in the US and GSK Consumer Healthcare medical sales representatives will begin meeting with doctors later this week to review clinical data showing the benefit of treating patients with Xenical.

"Our relationship with GSK is longstanding, and we are pleased to expand it further through the co-promotion of Xenical," commented Peter Hug, Head of Roche Pharma Partnering. "Through partnering, we have taken a highly effective Roche medicine and added GSK's OTC sales force, one of the strongest in the industry, to be competitive in a challenging market. Roche and GSK have a history of collaboration, a current agreement being the co-promotion of Boniva (ibandronate) for the management of osteoporosis."

"This is a great opportunity for GSK Consumer Healthcare. In July 2004, we also acquired the rights to orlistat over-the-counter (OTC) in the US. This new agreement enables us to get hands-on experience promoting prescription Xenical while we prepare our application to the FDA for an OTC version," commented George Quesnelle, President, GSK Consumer Healthcare North America. "Excess weight is a major healthcare threat among Americans and, as it is now recognized as a disease, we are hopeful that many more overweight and obese-people will seek medical help," he concluded.

Terms of the agreement

Under the terms of the agreement GSK obtains the exclusive right to detail and promote Xenical Rx in the US. The terms of the agreement remain confidential. This agreement is only valid in the US and does not affect any other market. Roche will continue to manufacture and invoice Xenical.

About Xenical

Xenical is the number one prescription weight loss medication worldwide that has a unique mode of action. It works locally in the gut to prevent dietary fat absorption by around 30 percent and effectively promotes weight loss. It is the most extensively studied pharmacological weight management treatment to date, with over 30,000 overweight or obese patients participating in clinical trials with Xenical, including the 4 year landmark XENDOS study. It is an effective therapy that not only helps patients lose weight, but also helps them maintain their weight loss.

About Obesity

According to the Centers for Disease Control and Prevention (CDC), about 2 out of 3 US adults are overweight or obese, suggesting that roughly 129 million people are at increased risk for developing type 2 diabetes, heart disease, some forms of cancer, and other disabling medical conditions.

About Roche-GSK collaborations

Roche and GSK were one of the first to adopt co-promotion in the US in the 1980's with Zantac. In July 2004, the parties entered into a licencing agreement for orlistat OTC in the US. In addition to expanding this relationship to include Xenical Rx in the US, the parties are co-promoting Boniva for the treatment of osteoporosis

About Roche

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About GlaxoSmithKline Consumer Healthcare

GlaxoSmithKline Consumer Healthcare is one of the world's largest over-the-counter consumer healthcare products companies. Its more than 30 well-known brands include the leading smoking cessation products, Nicorette and NicoDerm, as well as many medicine cabinet staples, Abreva,

Aquafresh, Sensodyne and Tums.

About GlaxoSmithKline

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

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Further information:

Roche: www.toche.com

GSK: www.gsk.som

Xenical: www.managingyourweight.com

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